UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,352	08/15/2001	Brian Cunningham	00-1123-D	3472

7590 07/02/2004

Lisa M. W. Hillman
McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,352	CUNNINGHAM ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-153* is/are pending in the application.

4a) Of the above claim(s) *20-50,53-58,70,75-99,102-109,126-128 and 147-153* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,51,52,59-69,71-74,100,101,110-125 and 129-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/04 - 5/04, 10/3
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

I. Applicant's amendment of claims 1, 5, 51, 52, 59, 67, 68, 101, 110, 114, 116, 133, 135 is acknowledged and has been entered.

1. Claims 1-19, 51, 52, 59-69, 71-74, 100, 101, 110-125, 129-146 are pending.

2. Claims 20-50, 53-58, 70, 75-99, 102-109, 126-128, 147-153 have been withdrawn from consideration.

Rejections Withdrawn

3. Applicant's arguments, see page 29, filed April 12, 2004, with respect to the objections of claims 51, 52, 59, 67, 101 have been fully considered and are persuasive. The objection of claims 51, 52, 59, 67, 101 has been withdrawn.

4. Applicant's arguments, see pages 31-35, with respect to the rejection of claims 1-19, 60-65, 68, 69, 100, 101, 110-125, 129-146 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims of 1-19, 60-65, 68, 69, 100, 101, 110-125, 129-146 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Information Disclosure Statement

II. The information disclosure statements (IDS) pointed out by applicant have been received and considered. The additional copies provided by applicant is greatly appreciated.

Claim Rejections - 35 USC § 112

III. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With respect to claim 51, applicant has recited an illuminating fiber probe connected to a detector, and a collection fiber probe connected to a light source. It is unclear how the illuminating fiber probe would illuminate when connected to a detector, and what the collection fiber probe would be collecting when connected to a light source.

Claim Rejections - 35 USC § 102

IV. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-19, 59-63, 110-119, 122, 125, 129-140, 143, 146 are rejected under 35 U.S.C. 102(e) as being anticipated by Budach et al [US 6,707,561].

With respect to claims 1, 9, 110, 114, 129, 133, Budach et al teach a two dimensional array comprising a sensor platform for use in sample analysis comprising a substrate of refractive index and a thin optically transparent layer of a greater refractive index. The grooves are formed on the surface of the optically transparent layer (column 5, lines 50-53). The superposition of several periodic structures which are parallel or perpendicular one with another, suitable for multiple wavelength use of the platform is also taught (column 5, lines 55-63). The surface of the

optically transparent layer may further include one or a plurality of corrugated sensing areas which each carry one or a plurality of capture elements (column 5, lines 63-68). The capture agents include antibodies and nucleic acids, and are adsorbed onto the sensor platform in spots with 150 μm diameters (column 23, lines 1-column 24, lines 39-67). The antigens and luminescence labeled secondary antibodies can be mixed in a pre-incubation step followed by incubating the sensor platform surface with the mixture.

Although applicant has further recited the limitation that when the biosensor is illuminated, a resonant grating effect is produced on a reflected radiation spectrum, wherein the depth and period of the two-dimensional grating are less than the wavelength of the resonant grating effect, as applicant has not recited any additional physical characteristics or properties that would be necessary for this to occur. Since the biosensors taught by Budach et al fulfill the physical limitations recited in a), b), and c), claim 1 as currently presented would read upon the biosensors taught by Budach et al.

8. With respect to claim 2, 111, 130, Budach et al teaches the feature of grooves, which act as gratings (column 5, lines 50-53). Gratings will inherently reflect a narrower band of optical wavelengths when illuminated with a band of optical wavelengths, as in any particular direction, only those waves of a given wavelength will be conserved, all the rest being destroyed because of interference with one another. Furthermore, applicant has not recited any additional specific physical characteristics that may be responsible for reflecting a narrow band of optical wavelengths. Since the array taught by Budach et al reads upon the biosensor as recited by applicant in the parent claims, claims 2, 111, and 130 would also be anticipated.

9. With respect to claim 3, 112, 115, 131, 134, the substrate can be formed from glass (column 4, lines 59-63).

10. With respect to claim 4, 113, 116, 132, 135, the optical transparent coating can be tantalum oxide (column 5, lines 9-14).

11. With respect to claims 5-7, 136-137, Budach et al further teach an adhesion promoting layer disposed at the surface of the optically transparent layer for immobilization of capture molecules, comprising glass (column 6, lines 20-31).

12. With respect to claims 8, 119, 140 the grooves taught by Budach et al have a period of 200 to 1000 nm and a depth of 3 nm to the thickness of the optical transparent layer.

13. With respect to claims 10-16, the capture agents include antibodies and nucleic acids, and are adsorbed onto the sensor platform in spots with diameters of 150 μm (column 23, lines 1-column 24, lines 39-67). The antigens and luminescence labeled secondary antibodies can be mixed, followed by incubating the sensor platform surface with the mixture.

14. With respect to claims 17, 18, Budach et al teach that the platform can also be adapted to microtiter-type plates/devices in order to perform one or multiple assays in the individual microtiter wells, wherethe plate types can comprise 96, 384, 1536 or higher numbers of wells (column 18, lines 37-42).

15. With respect to claim 19, 122, 143, Budach et al further teach a laser light source, a detector, and a polarizer (column 10, lines 37-60).

16. With respect to claims 59-62, 66, Budach et al teach that the platform can also be adapted to microtiter-type plates/devices in order to perform one or multiple assays in the individual microtiter wells, where the plate types can comprise 96, 384, 1536 or higher numbers of wells

(column 18, lines 37-42). Each well would be considered an individual sensing area or biosensor (column 18, lines 31-34), associated with the microtiter plate (holding fixture) (figs. 8e, 8g).

17. With respect to claim 63, the biosensors each comprise one or multiple capture elements. Budach et al further clarifies that a sensing area can comprise 1 to 1,000,000 capture elements, each which would be considered a distinct location (column 6, lines 10-15).

18. With respect to claims 64, 65, Budach et al teach that the size of an individual capture element is between 1 μm^2 and 1 mm^2 (column 6, lines 1-9). Since each sensing area (biosensor) can comprise 1 to 1,000,000, each sensing area would be between 1 μm^2 and 1,000,000 mm^2.

19. With respect to claims 117, 118, 138, 139, the two-dimensional grating is comprised of repeating circles arranged in rectangular grid (figs 8a-8g).

20. With respect to claims 125, 146, the laser light source is directed toward the platform by means of a dichroic member, and illuminates the surface of the platform from the top or bottom (fig. 6, column 20, lines 56-67).

Claim Rejections - 35 USC § 103

V. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Linnecke et al [US 4,240,751].

Budach et al teach a detection system comprising a light source that directs light at the biosensor and a detector that detects light reflected from the biosensor, as discussed above. Budach et al do not teach a fiber probe connected at one end to a detector and a second fiber probe connected to a light source, and a third fiber probe connected to the first and second fiber probes, where the third fiber probe supports counter-propagating illuminating and reflecting optical signals.

Linnecke et al, however do teach a fiber probe connected at one end to a detector and a second fiber probe connected to a light source (column 9, lines 49-65), and a third fiber probe connected to the first and second fiber probes, where the third fiber probe supports counter-propagating illuminating and reflecting optical signals and is oriented at a normal angle of incidence to the biosensor (fig.9). Linnecke et al further teach that this allows for substantially uniform light in a predetermined wavelength band to be provided (column 9, lines 49-55), as well as receiving primarily diffuse reflected light from the sample for analysis (column 11, lines 1-5). Linnecke et al further teach that the apparatus can be operated at ambient conditions of temperature, pressure, and humidity in an ordinary light-filled room, and has the advantage of no moving parts and mechanical adjustments (column 11, lines 36-41).

Therefore it would have been obvious to have a fiber probe connected at one end to a detector and a second fiber probe connected to a light source, and a third fiber probe connected to the first and second fiber probes, where the third fiber probe supports counter-propagating illuminating and reflecting optical signals, in order to provide an apparatus that can be operated at ambient conditions of temperature, pressure, and humidity in an ordinary light-filled room, and has the advantage of no moving parts and mechanical adjustments.

22. Claims 52, 123, 124, are rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Siminovitch [US 6,128,431]

With respect to claims 52, 123, 144, Budach et al teach a biosensor, a detector that detects light reflected from the biosensor, and a light source that directs light at the biosensor at a 90 degree angle from the light detected by the detector, and a beam splitter (fig. 6). Lenses are also used (column 10, lines 36-46). Budach et al do not teach a fiber probe connected to the light source, and a fiber probe connected to the detector.

Siminovitch, however, teaches that fiber optic waveguides allow light to be transmitted over long distances without substantial loss (column 1, lines 40-43). Therefore it would have been obvious to have fiber probes connected to the light source and detector, in order to allow light to be transmitted over long distances, without substantial loss.

23. Claims 67-69, are rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Walt et al [US 6,200,737].

With respect to claims 67-69, Budach et al teach that the platform can also be adapted to microtiter-type plates/devices in order to perform one or multiple assays in the individual microtiter wells, where the plate types can comprise 96, 384, 1536 or higher numbers of wells (column 18, lines 37-42). Budach et al fail to teach that the biosensors are attached to an optical fiber probe.

Walt et al do teach biosensors comprising optical fiber probes comprising multiple optical strands (column 5, lines 18-35), with polymeric structures such as diffraction gratings attached to the ends (column 6, lines 20-25). Walt et al further teach that these arrays have many

uses due to their ease of fabrication, the diversity of polymer functionality, and allows for high loadings of immobilized molecules (column 20, lines 15-20).

Therefore it would have been obvious in the method of Budach et al to utilize optical fibers, as taught by Walt et al, due to their ease of fabrication, the diversity of polymer functionality, and the ability for high loadings of immobilized molecules.

24. Claims 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Svetkoff et al [US 5,768,461].

With respect to claims 71-72, Budach et al teach the use of a detection system comprising a biosensor and a laser source and a mirror. Budach et al do not teach that the mirror is a linear galvanometer.

Svetkoff et al, however, teach that linear galvanometer can provide both video rate capability and addressability (column 12, lines 44-60). Therefore it would have been obvious in the method of Budach et al to use a linear galvanometer in order to provide both video rate capability and addressability.

25. Claim 73 is not given any patentable weight, as it refers to an intended use of the linear galvanometer. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masha*, 2 USPQ2d 1647 (1987). In particular, the limitation refers to the frequency and scan angle that the galvanometer would operate at. Since the linear galvanometer taught by Svetkoff et al would be capable of operating at a frequency of about 2 Hz to about 120 Hz, with a mechanical scan angle of about 10 degrees to about 20 degrees, the prior art would read upon claim 73.

26. With respect to claim 74, Budach et al teach the use of diode lasers (column 7, lines 5-10). Budach et al further teach that the wavelength of the light will be between 350 nm to 1000 nm (column 10, lines 37-46).

27. Claims 100, 120, 121, 141, 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Hobbs et al [US 6,185,019].

Budach et al teaches the use of a sensor array as discussed above. Budach et al does not teach the use of anti-reflective "moth-eye" structures.

Hobbs et al, however, do teach the use of motheye surface structures with gratings and that motheye surface structures have been shown to be effective for nearly eliminating the reflectance of light from an optical interface such as between air and a window or a refractive optical element (column 4, lines 1-4).

Therefore, it would be obvious to use anti-reflective "moth-eye" structures in the biosensor of Budach et al, as taught by Hobbs et al, for nearly eliminating the reflectance of light from an optical interface such as between air and a window or a refractive optical element.

28. Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Rudigier et al [US 5,738,825].

Budach et al teach that the biosensor which can be adapted to microtiter plates or devices (column 18, lines 36-42). Budach et al do not, however, teach that the biosensor is attached to a bottomless microtiter plate.

Rudiger et al do teach that a base plate containing a diffraction grating (biosensor) can be releasibly fixed to the sample plate, such that a separate diffraction grating means may be

provided beneath each well (column 2, lines 35-48). Rudiger et al further teach that this allows the base plate to be detached from the sample plate and replaced.

Therefore it would have been obvious to attach the biosensor to a bottomless microtiter plate, so allow the biosensor to be later detached from the plate and replaced.

Claims 123-124, 144-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budach et al [US 6,146,593] in view of Pinkel et al [US 6,146,593].

With respect to claim 123, 144, Budach et al teach a detection system comprising a light source, a detector and a biosensor array, as dicussed above. Budach et al do not teach fiber probes connected to the light source or probes connected to the detector.

Pinkel et al, however, teach a detection system comprising a biosensor, and fiber probes connected to a detector and light source. Light is transmitted from the light source through the fibers until it reaches the sensor ends of the fibers and to the biosensor (column 14, lines 39-51). Optical signals produced can then be transmitted from the sensor ends to the transmission ends and to a detector (column 3, lines 27-38). Pinkel et al further teach that the use of optical fibers allows for simultaneous measurement of the binding of a multiplicity of analytes (column 3, lines 28-32).

Response to Arguments

29. Applicant's arguments with respect to claims 1-19, 51, 52, 59-69, 71-74, 100, 101, 110-125, 129-146 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

30. No claims are allowed.

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
06/12/07